FDA's Plans for Post-utilization Adverse Event Monitoring for Influenza A(H1N1) vaccines

Presented by:

Hector S. Izurieta

Chief, Analytical Epidemiology Branch

DE/OBE/CBER

Safety Evaluations/Surveillance: Passive Surveillance

- FDA and CDC are working to improve efficiency of reporting and analysis processes.
  - Improve processes, data mining, electronic submissions from manufacturers, improved internet reporting, potential use of report cards to enhance reporting, etc.

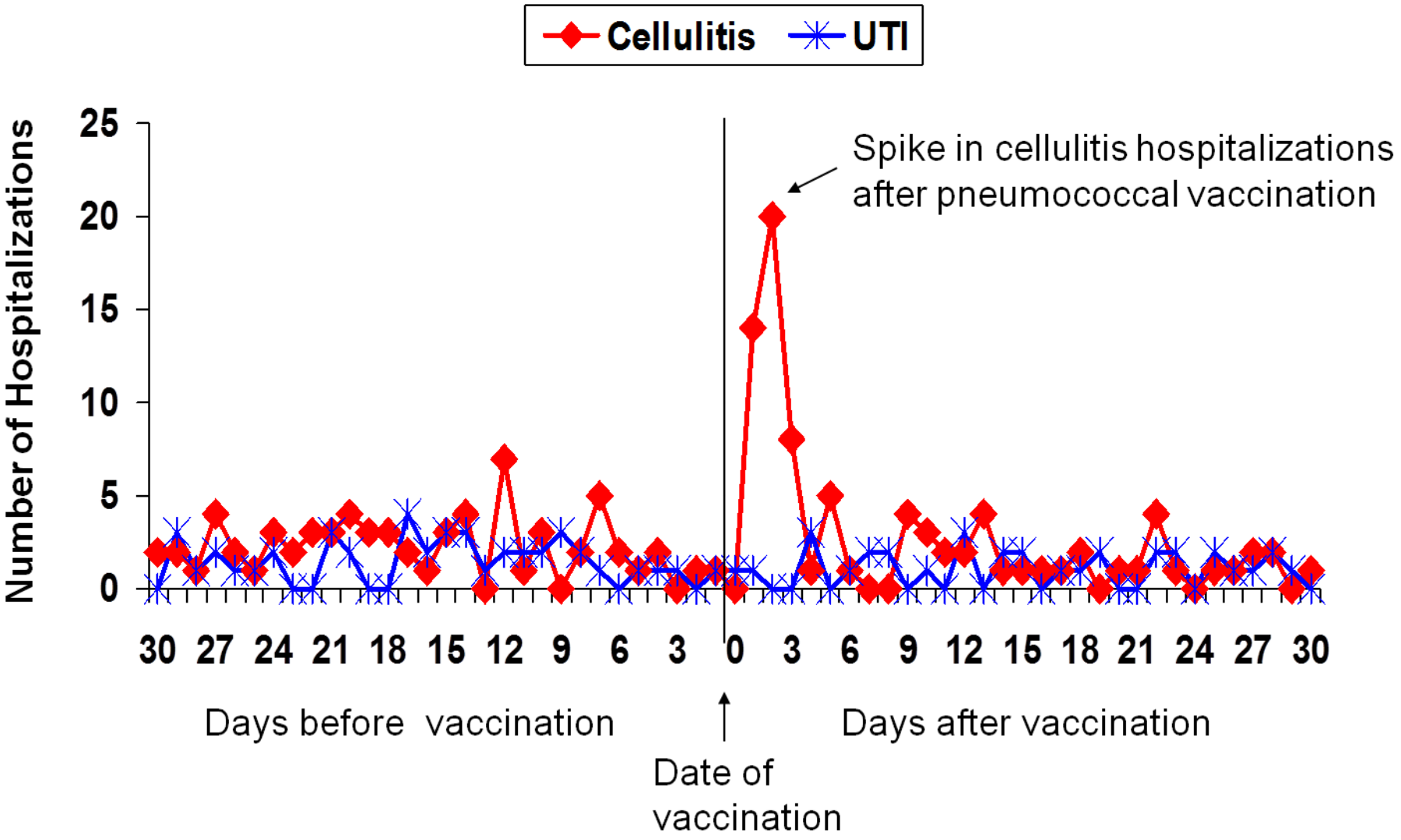
Safety Evaluations: Pharmacoepidemiology, VSD Studies

- Pharmacoepidemiologic analyses for safety and field effectiveness will depend on reliable linkages between each person's individual's specific vaccine information and subsequent medical events
- FDA will collaborate with CDC in the use the Vaccine Safety Datalink (VSD) for rapid cycle analyses of pre-specified adverse events, including GBS and anaphylaxis, and potentially perform safety evaluation for non-pre-specified risks, contingent, again, on essential data linkages.
  - Expanded resources could increase the numbers of HMO sites that can work with the VSD and could strengthen or create data linkages with state immunization registries.

FDA work with Medicare: Background

- Approximately 45 million persons enrolled, including
  - 38 million elderly (age ≥65 years)
  - 7 million others with disability or end stage renal disease
  - Individual health utilization data available for the approximately 85-90% enrolled in fee-for-service Medicare
  - Prescription drug benefit started 2006
- FDA can monitor CMS claims for GBS and anaphylaxis using near-real time techniques, provided the data include specific vaccine exposures (e.g., distinguishing between seasonal flu vs. 2009 H1N1 products).

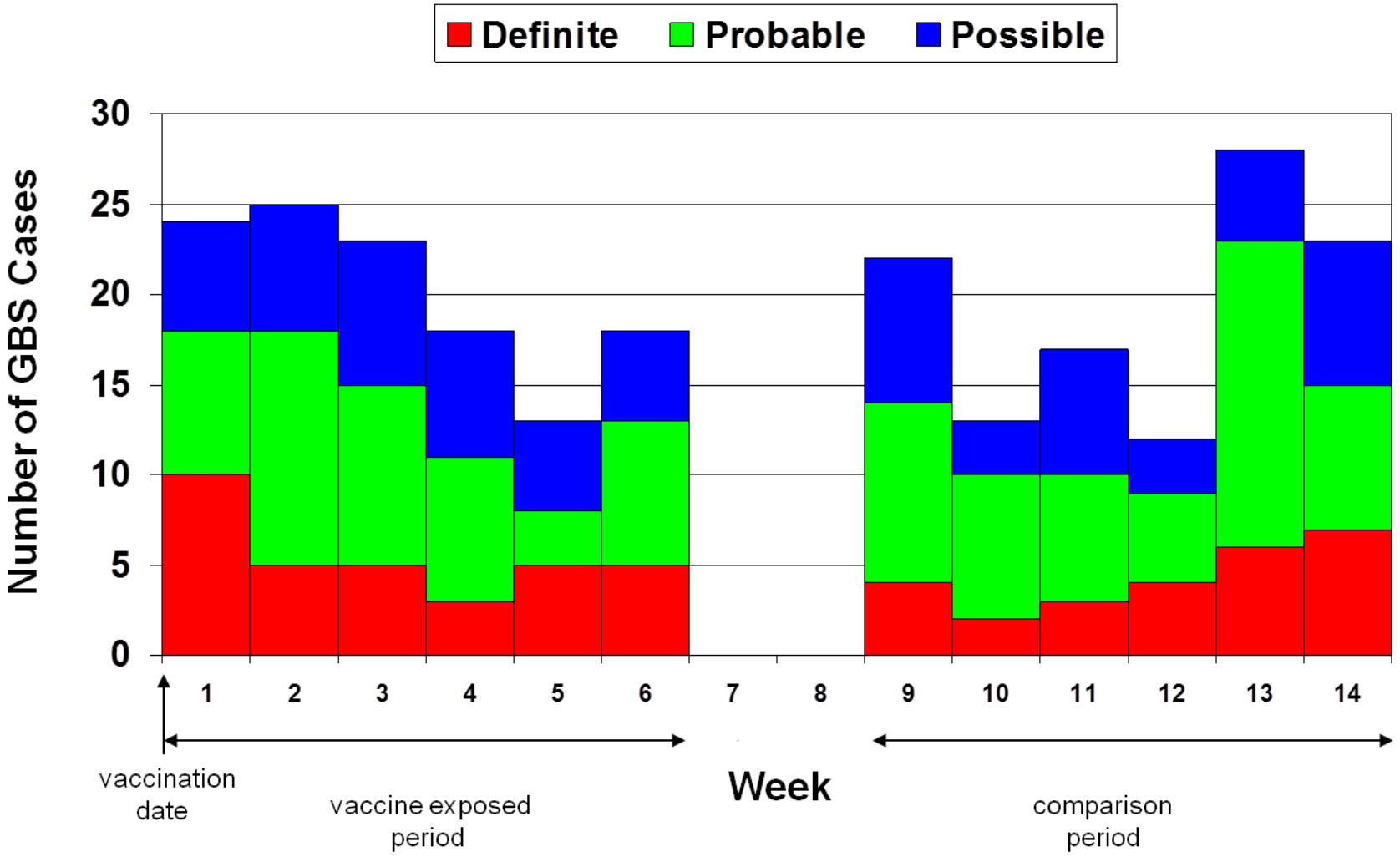
Hospitalizations for Cellulitis or Urinary Tract Infection (UTI)* Within the 30 Days Before or After Pneumococcal Vaccination†



* UTI 5% Sample

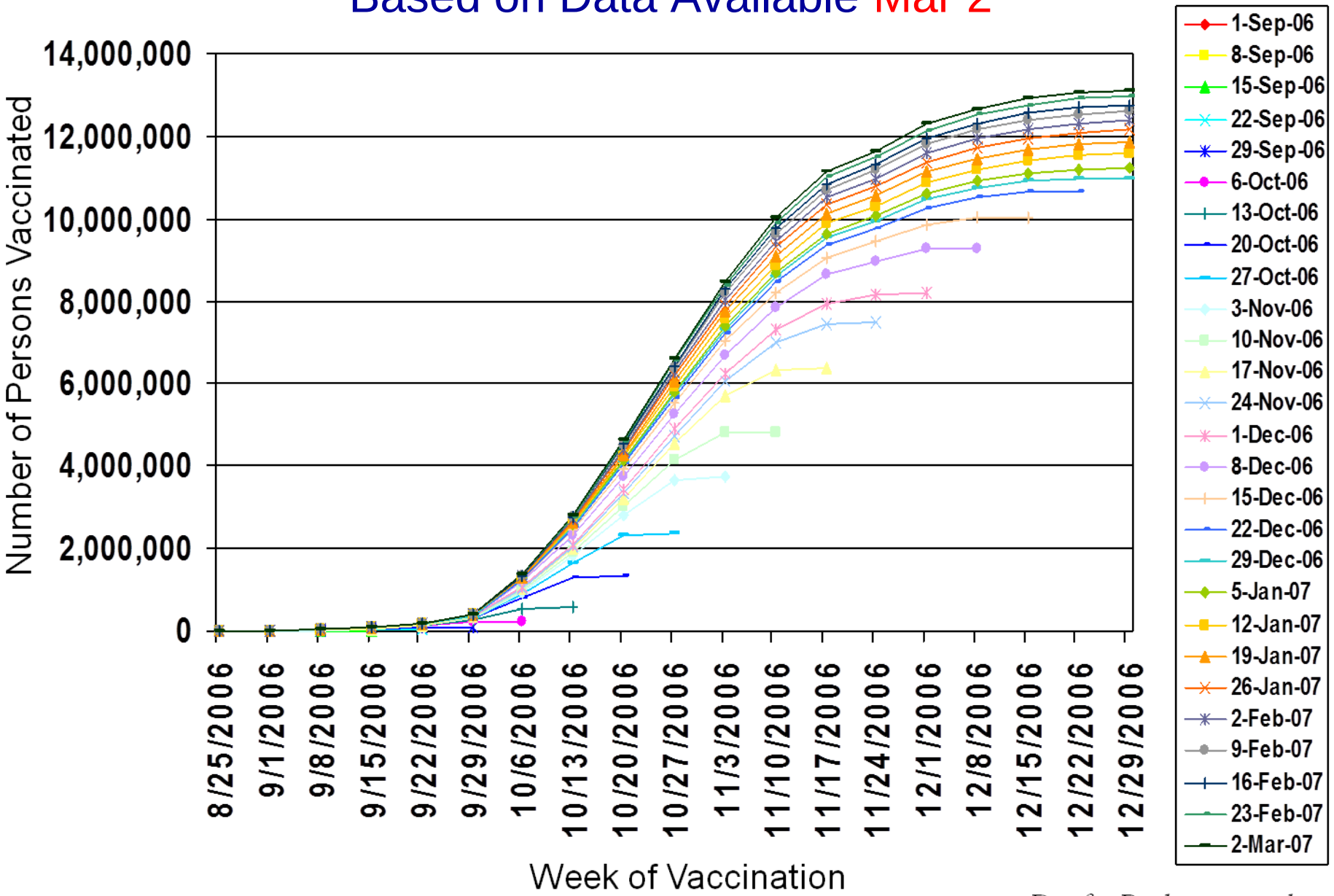
† Among 1.7 million persons vaccinated, 2001 data

Distribution of GBS cases (by onset date) after influenza vaccine among persons vaccinated during September through December, 2000 and 2001



Draft. Preliminary results.

Cumulative Influenza Vaccinations, Based on Data Available Mar 2



Draft. Preliminary data.

Safety Evaluations: DoD/MILVAX Collaborations

- FDA has initiated collaboration with DoD MILVAX and Health Affairs for enhanced surveillance of vaccine safety in >1.5 million active duty military personnel.
  - An initial research plan is being drafted (and will be sent to CDC and other partners for feedback). It includes:
  - An enhanced surveillance component for identification of signals using a pre-specified list of outcomes (dependent on the timeliness of electronic medical records availability)
  - A case control and a cohort approaches for signal verification. Based on preliminary information, we expect the necessary linkages between specific vaccination data and subsequent health events to be available.

Safety Evaluations: Other Activities

- FDA will continue to discuss potential additional contributions that manufacturers could make to safety surveillance.
- FDA could use its outside research contract capabilities to implement other enhanced surveillance efforts
- Collaboration with others (Tricare, VA) for rapid surveillance is being explored
- International collaboration:
  - FDA has initiated collaboration with EMEA, the Canadian regulatory authorities and Health Canada, for coordination of pharmacovigilance activities and information exchange.
  - FDA and CDC also expect to collaborate with international organizations, via the World Health Organization (WHO), PAHO and others, to foster technical collaboration on H1N1 vaccines adverse event investigation.